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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 25-JUL-2007

Subject: PP#6F7031. **Sulfosulfuron**. New Uses on Grass Forage, Fodder, and Hay (Crop Group 17). Summary of Analytical Chemistry and Residue Data.

DP#: 328450 Decision#: 364046
PC Code: 085601 MRID#: 46753801
40 CFR 180. 552
Chemical Class: Sulfonylurea herbicide

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This document was originally prepared under contract by Dynamac Corporation (2275 Research Blvd, Suite 300; Rockville, MD 20850; submitted 12-JUL-2006). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

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Executive Summary

Sulfosulfuron (*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-2-(ethylsulfonyl)imidazo[1,2-*a*]pyridine-3-sulfonamide) is a selective broadleaf sulfonylurea herbicide registered for control of grass and broadleaf weeds in spring and winter wheat. Sulfosulfuron exhibits systemic postemergence herbicidal activity on a broad spectrum of annual and perennial sedges, grasses, and broadleaf weeds, but does not injure many warm-season and some cool-season grasses. Data for sulfosulfuron were originally reviewed by HED under a petition for use on wheat (Memo, S. Chun, 28-SEP-1998; DP#: 237683). Sulfonylurea herbicides disrupt amino acid biosynthesis in susceptible plants by binding to the acetolactate synthase (ALS) enzyme.

Monsanto Company has proposed to amend the use pattern for the 75% water-dispersible granule (WDG) formulation of sulfosulfuron (Maverick® Herbicide; EPA Reg. No. 524-500) to include uses on grasses. The proposed uses include postemergence broadcast application to Bermudagrass and bahiagrass at a maximum seasonal rate of 0.125 pounds active ingredient per acre (lb ai/A), with a 0-day pre-harvest interval (PHI) for forage and a 14-day PHI for hay.

In conjunction with the amended use request, Monsanto has proposed, in PP#6F7031, the establishment of permanent tolerances for the residues of sulfosulfuron and its metabolites calculated as sulfosulfuron, in/on the following raw agricultural commodities (RACs):

Grass forage	13 ppm
Grass hay	14 ppm

As a result of the proposed uses on grass forage and hay, Monsanto has also proposed revisions to the established tolerances for sulfosulfuron and its metabolites calculated as sulfosulfuron for the following livestock commodities:

Cattle, fat	0.03 ppm
Cattle, meat	0.01 ppm
Cattle, meat byproducts	0.4 ppm
Goat, fat	0.03 ppm
Goat, meat	0.01 ppm
Goat, meat byproducts	0.4 ppm
Horse, fat	0.03 ppm
Horse, meat	0.01 ppm
Horse, meat byproducts	0.4 ppm
Sheep, fat	0.03 ppm
Sheep, meat	0.01 ppm
Sheep, meat byproducts	0.4 ppm
Milk	0.02 ppm

Permanent and time-limited tolerances for residues of sulfosulfuron in/on raw agricultural and livestock commodities are established under 40 CFR §180.552(a) and 40 CFR §180.552(b), respectively and are expressed in terms of residues of sulfosulfuron and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine, calculated as sulfosulfuron. Permanent tolerances are established for wheat commodities at 0.02-4.0 ppm, and tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are established at 0.005-0.05

ppm. Time-limited tolerances are established for Bahiagrass and Bermudagrass forage and hay commodities at 11-40 ppm, and tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are established at 0.02-0.50 ppm, set to expire 31-DEC-2009.

The qualitative nature of the residue in cereal grains and livestock is adequately understood based on acceptable wheat, goat, and hen metabolism studies. In all studies the primary residues were the parent and those metabolites containing the intact imidazopyridine ring. HED has concluded that the residues of concern in wheat and livestock commodities, for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine (or the ethyl sulfone chemophore). The HED risk assessment team concludes that the results of the wheat metabolism study may be translated to grass and that the residues of concern in grass, for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine.

In support of the petition for use on wheat, the petitioner proposed two common-moiety high-performance liquid chromatography (HPLC) methods with fluorescence detection for enforcement of tolerances in wheat and livestock commodities. In these methods, residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring are converted by acid hydrolysis to the ethyl sulfone chemophore. Samples from the submitted grass field trials were analyzed for residues of sulfosulfuron and metabolites containing the intact imidazopyridine ring using a common moiety liquid chromatograph/mass spectrometry/mass spectrometry (LC/MS/MS) method that was adapted from the proposed enforcement method for wheat. The validated limit of quantitation (LOQ) was 0.005 ppm, and the limit of detection (LOD) was 0.0026 ppm. The method is adequate for data collection based on acceptable concurrent recovery data.

The revision of the original HPLC enforcement method to use LC/MS detection resolves the previous deficiencies related to specificity and confirmatory method. These deficiencies are no longer outstanding. The plant LC/MS/MS method was sent to the Analytical Chemistry Laboratory (ACL) for a petition method validation (PMV) (Memo, S. Levy, 17-OCT-2006; DP# 332807). The final decision regarding the adequacy of the revised analytical enforcement method for plants is pending upon successful completion of a PMV by the ACL. Analytical standards for sulfosulfuron are currently available in the National Pesticide Standards Repository; however analytical standards for the ethyl sulfone chemophore metabolite of sulfosulfuron are not available (personal communication, Dynamac with D. Wright, 07-JUN-2006). **This is a deficiency.** Analytical reference standards of the ethyl sulfone metabolite should be supplied, and supplies for the analytical standards for sulfosulfuron and its ethyl sulfone metabolite should be replenished as requested by the Repository.

The maximum storage intervals of crop samples from harvest to analysis were 326 days (10.7 months) for grass forage and 300 days (9.9 months) for grass hay. Acceptable storage stability data are available which indicate that residues of sulfosulfuron are stable under frozen storage conditions in/on fortified samples of wheat forage for up to 17.5 months. These data may be translated to grass forage and hay, and are adequate to support the storage intervals of samples from the grass field trials.

The proposed uses on grasses include ruminant feed items. Because residues in/on grass forage and hay resulting from the proposed use were significantly higher than those observed for wheat commodities, there is an appreciable increase in the maximum theoretical dietary burden (MTDB) for ruminants. Based on the results of the available feeding study and the recommended tolerances for grass forage and hay, the following tolerances for livestock commodities (*i.e.*, of cattle, goat, horse, and sheep) are appropriate: 0.02 ppm for fat and milk, 0.01 for meat, 0.30 ppm for meat byproducts (see Table 7). **A revised Section F should be submitted.**

The submitted grass crop field trial data adequately reflect the proposed use pattern with respect to application rate, timing of applications, and harvest intervals; geographic representation is adequate. However, the proposed use pattern specifies that a nonionic surfactant is required, and the submitted data do not reflect use of a spray adjuvant. Provided the petitioner amends the proposed supplemental labeling for grasses by removing directions for use of a nonionic surfactant, or provides residue data that includes use of a nonionic surfactant, the available field trial data will support tolerances for residues of sulfosulfuron and its metabolites in/on grass forage and hay. HED notes that the tolerance for grass forage was based on examination of residue results reflecting a single application at 0.094 lb ai/A because the highest residues observed in the field trials occurred following this use pattern. These data indicate that the proposed tolerances of 13 ppm for grass forage and 14 ppm for grass hay are too low and should be increased to 14 ppm and 25 ppm, respectively. The proposed tolerances should be revised to reflect the recommended tolerance levels and correct commodity definitions as specified in Table 7. **A revised Section F should be submitted.**

The nature of the residue in rotational crops is understood. HED concluded that the residues of concern in rotational crops for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine (or the ethyl sulfone chemophore). A limited field rotational crop study (MRID 44821802) on sulfosulfuron has been submitted and reviewed to support the registration on wheat (Memo, P. Errico, 21-JAN-2000; No DP#). This study, along with a confined rotation study (MRID 44295735) showed that uptake of sulfosulfuron residues from the soil by root and tuber, leafy vegetable, and small cereal grain crops is minimal. Even with a plant-back interval (PBI) of 7 days (root/tuber crop), no residues of sulfosulfuron or its metabolites were detected above the LOD of 0.006 ppm in the field rotational crop study, when planted into soil that had been treated at 0.035 lbs ai/A. For grass pastures, the seasonal application rate is 1.2 lbs ai/A, or ~ 4 times greater than the study conditions. At the seasonal application rate, and assuming a linear application rate/residue concentration correlation, the expected residue concentrations at the higher application rate would be less than 0.024 ppm. Because the label has a 12 month minimum PBI, residues in rotational crops are not expected.

There are no established or proposed Codex or Mexican maximum residue limits (MRLs) for residues of sulfosulfuron in grasses or wheat. There are no established Canadian MRLs for residues of sulfosulfuron in grasses; a Canadian MRL has been established for sulfosulfuron residues in wheat. Therefore, there are no harmonization issues with respect to the proposed uses on grasses.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of a revised Sections B (see requirements under Directions for Use) and F (see requirements under Proposed Tolerances) and submission of analytical standards for the ethyl sulfone chemophore metabolite of sulfosulfuron to the National Pesticide Standards Repository, there are no residue chemistry issues that would preclude granting a conditional registration for the requested uses of sulfosulfuron on grasses, or establishment/revision of tolerances for residues of sulfosulfuron and metabolites as follows:

Grass, forage, fodder and hay, group 17, forage	14	ppm
Grass, forage, fodder and hay, group 17, hay	25	ppm
Cattle, fat	0.02	ppm
Cattle, meat	0.01	ppm
Cattle, meat byproducts	0.30	ppm
Goat, fat	0.02	ppm
Goat, meat	0.01	ppm
Goat, meat byproducts	0.30	ppm
Horse, fat	0.02	ppm
Horse, meat	0.01	ppm
Horse, meat byproducts	0.30	ppm
Sheep, fat	0.02	ppm
Sheep, meat	0.01	ppm
Sheep, meat byproducts	0.30	ppm
Milk	0.02	ppm

Conversion from a conditional to an unconditional registration is contingent upon submission of a successful completion of a PMV by the ACL.

A human-health risk assessment will be prepared as a separate document.

860.1200 Directions for Use

- The petitioner should amend the proposed supplemental labeling for grasses by removing directions for use of a nonionic surfactant, or provide residue data that includes use of a nonionic surfactant.

- The supplemental labeling should be revised to reflect the information contained in Section B of the petition materials concerning the maximum number of applications per season (two) and the timing of applications (from early spring through the fall).

860.1340 Residue Analytical Methods

- Successful completion of a revised enforcement method is pending upon successful completion of a PMV by ACL.

- Analytical standards for the ethyl sulfone chemophore metabolite of sulfosulfuron are not available in the National Pesticide Standards Repository. Analytical reference standards

of the ethyl sulfone metabolite should be supplied, and supplies for the analytical standards for sulfosulfuron and its ethyl sulfone metabolite should be replenished as requested by the Repository

860.1500 Crop Field Trials

- The petitioner should amend the proposed supplemental labeling for grasses by removing directions for use of a nonionic surfactant, or provide residue data that includes use of a nonionic surfactant.

860.1550 Proposed Tolerances

- The petitioner should submit a revised Section F reflecting the HED-recommended tolerance levels and correct commodity definitions as specified in Table 7.

- The petition should modify the proposed tolerance expression to reflect the expression stated in 40 CFR 180.552: "residues of the herbicide sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-*a*]pyridine-3-yl) sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine and calculated as sulfosulfuron."

Background

The chemical structure and nomenclature of sulfosulfuron are presented in Table 1. The physicochemical properties of the technical grade of sulfosulfuron are presented in Table 2.

Table 1. Sulfosulfuron Nomenclature.

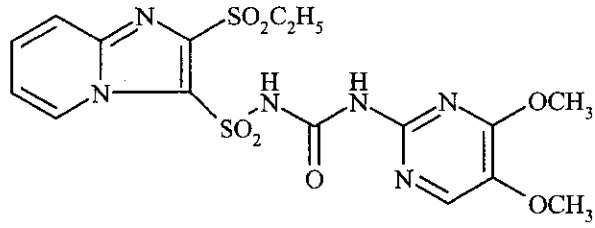
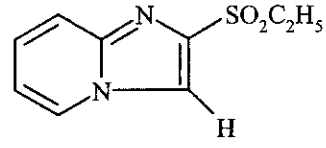
Chemical structure	
Common name	Sulfosulfuron
Company experimental name	MON 37500; TKM-19
IUPAC name	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-ethylsulfonylimidazo[1,2-*a*]pyridin-3-ylsulfonyl)urea
CAS name	*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-2-(ethylsulfonyl)imidazo[1,2-*a*]pyridine-3-sulfonamide
CAS registry number	141776-32-1
End-use product (EP)	75% WDG (Maverick® Herbicide; EPA Reg. No. 524-500)
Chemical structure of ethyl sulfone chemophore	 2-(ethylsulfonyl)-imidazo [1,2-*a*]pyridine

Table 2. Physicochemical Properties of Sulfosulfuron.

Parameter	Value	Reference
Melting range	180.9-184.1°C	MRID 44295704; Memo, S. Chun, 28-SEP-1998; DP#: 237683
pH	4.76	
Density	1.55 g/mL at 20°C	
Water solubility	ppm at 20°C pH 5 17.60 ± 2.71 pH 7 1626.8 ± 39.8 pH 9 482.44 ± 8.35	
Solvent solubility	ppm at 20°C Heptane <1 Xylene 160 Methanol 330 Ethyl acetate 1010 Dichloroethane 4350	
Vapor pressure	2.29×10^{-10} mm Hg at 20°C 6.61×10^{-10} mm Hg at 25°C	
Dissociation constant, pK_a	pK_a = 3.51 at 20°C	
Octanol/water partition coefficient, Log (K_{OW})	pH 5: K_{OW} = 6.38; pK_{OW} = 0.81 pH 7: K_{OW} = 0.14; pK_{OW} = -1.01 pH 9: K_{OW} = 0.036; pK_{OW} = -1.37	

Table 2. Physicochemical Properties of Sulfosulfuron.		
Parameter	Value	Reference
UV/visible absorption spectrum	UV_{MAX} = 208 nm ε = 187,150 L/mol cm (pH >10.0, 1.06% by weight in water, 26°C)	

860.1200 Directions for Use

The petitioner has included use directions for the 75% WDG formulation of sulfosulfuron (Maverick® Herbicide; EPA Reg. No. 524-500) under Section B of the petition as well as a copy of the proposed supplemental labeling for use on Bermudagrass and bahiagrass. The proposed uses are presented in Table 3.

Table 3. Summary of Directions for Use of Sulfosulfuron.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Bermudagrass and Bahiagrass[1]						
Postemergence; Broadcast; Ground or Aerial	75% WDG [524-500]	0.094	**2**	0.125	0 forage 14 hay	For use in well-established pastures. **Applications may be made from early spring through the fall**; follow-up applications may be made after suitable regrowth of weeds but no sooner than 40 days after initial application. Addition of a nonionic surfactant (NIS) at 0.25% by volume is required. Use only NISs containing ≥90% active ingredient which will not alter the pH of the spray solution to <5.

[1] **Bolded** information appears in Section B, but not on the proposed supplemental labeling.

The supplemental label also contains the following statement concerning rotational crops: "No crop, except wheat, may be planted into pastures that have been treated with this product within 12 months after application. All crops other than wheat may be seeded only after completion of a successful field bioassay."

The master label for the 75% WDG formulation (accepted 7/11/05) includes the following general use directions. Applications may be made using ground or aerial (fixed-wing or helicopter) equipment. Ground applications are to be made in 5-20 gallons of water per acre or 10-40 gallons of liquid fertilizer solution per acre, and aerial applications are to be made in 5-15 gallons of water per acre. Spray solutions of pH 6-8 are optimum; 7% ammonia solution may be used to increase the pH of the spray solution to the optimum range. Applications through any

type of irrigation systems are prohibited. In addition, HED notes that the master label states that a nonionic surfactant is required in the spray solution for postemergence applications.

Conclusions. The submitted information concerning the proposed use pattern is adequate to allow evaluation of the submitted data for grasses. The submitted crop field trial data for grasses do not support the proposed use directions because the supplemental label states that use of a nonionic surfactant is required, and, based on the information contained in MRID 46753801, no adjuvant was used in the field trials. The petitioner should amend the proposed supplemental label for grasses by removing directions for use of a nonionic surfactant, or provide residue data that includes use of a nonionic surfactant

In addition, the supplemental labeling should be revised to reflect the information contained in Section B of the petition materials concerning the maximum number of applications per season (two) and the timing of applications (from early spring through the fall). **A revised Section B should be submitted.**

860.1300 Nature of the Residue - Plants

Memo, L. Cheng, 22-AUG-1997; No DP#
Memo, S. Chun, 28-SEP-1998; DP#: 237683
Memo, S. Chun, 23-NOV-1998; DP#: 249043
Memo, T. Bloem, 04-AUG-2004; DP#: 306356

The qualitative nature of the residue in wheat is adequately understood for purposes of this petition based on an acceptable wheat metabolism study. The study reflected separate application of two test substances: sulfosulfuron ^{14}C-labeled at the C-3 position of the imidazopyridine ring (Im-MON 37500) and a mixture of sulfosulfuron ^{14}C-labeled at the C-5 position of the pyrimidine ring and sulfosulfuron ^{15}N-labeled at the amino nitrogen of the aminopyrimidine ring (Pd-MON 37500). Based on the submitted study, HED concluded that the sulfonylurea bond is cleaved in the soil prior to uptake by the plant, and that metabolites containing the imidazopyridine ring (Im-metabolites) are more readily taken up by the plant than those containing the pyrimidine ring (Pd-metabolites). Metabolite formation appears to occur by demethylation and cleavage of the sulfonylurea bond.

HED Metabolism Assessment Review Committee (MARC) concluded that the residues of concern in wheat commodities, for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine (or the ethyl sulfone chemophore) (Memo, S. Chun, 23-NOV-1998; DP# 249043).

In connection with data review for a Section 18 Specific Emergency Exemption for application of sulfosulfuron to Bermudagrass and bahiagrass, HED previously concluded that the results of the wheat metabolism study may be translated to grass.

860.1300 Nature of the Residue - Livestock

Memo, S. Chun, 28-SEP-1998; DP#: 237683
Memo, S. Chun, 23-NOV-1998; DP#: 249043

The qualitative nature of the residue in livestock is adequately understood based on acceptable studies with goats and hens. Studies on goats and hens were conducted using the Im-MON 37500 and Pd-MON 37500 test substances. The metabolism of sulfosulfuron in livestock appears to proceed via demethylation (most likely oxidative) of one of the methoxy groups to form desmethyl sulfosulfuron and cleavage of the sulfonylurea bridge to form a sulfonamide metabolite. Cleavage of the sulfonylurea bridge, oxidation of the aminopyrimidine ring at the 5-position, and sulfonation of the aminopyrimidine 5-hydroxy group to form pyrimidine sulfate was also observed in goats; hydroxylation of the aminopyrimidine ring at the 5-position to form 5-hydroxy-sulfosulfuron was also observed in hens.

HED concluded that the residues of concern in livestock commodities, for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine (or the ethyl sulfone chemophore).

860.1340 Residue Analytical Methods

Memo, S. Chun, 28-SEP-1998; DP#: 237683
Memo, S. Chun, 31-MAR-1999; DP#: 252646
Memo, S. Chun, 21-APR-1999; DP#: 254305

Enforcement methods: Acceptable enforcement analytical methods are available through the ACL. In support of the petition for use on wheat, the petitioner proposed two common moiety HPLC methods with fluorescence detection for enforcement of tolerances in wheat and livestock commodities. In these methods (Method RES-082-94, Version 2, for wheat, and Method RES-095-96, Version O, for livestock commodities) residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring are converted by acid hydrolysis to the ethyl sulfone chemophore. Adequate radiovalidation and independent laboratory validation data were provided for both methods; however, the methods failed the PMV by ACL. ACL developed a revised procedure that was acceptable, and the petitioner was advised to revise the methods per ACL's recommendations and submit the revised method for a new PMV. In the meantime, ACL agreed to provide instructions to any state lab requesting the method. Confirmatory methods and a specificity study were also required.

Data collection method: Samples from the submitted grass field trials were analyzed for residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring using a common moiety LC/MS/MS method that was adapted from the proposed enforcement method for wheat. In the method, residues of sulfosulfuron and its metabolites are hydrolyzed to the ethyl sulfone chemophore. Modifications included use of LC/MS/MS analysis instead of HPLC with fluorescence detection and elimination of the amino solid-phase extraction (SPE) cleanup step.

Briefly, homogenized samples were extracted with acetonitrile (ACN):water (1:1, v:v). The extract was filtered, concentrated, and refluxed with HCl overnight. The hydrolyzed extract was adjusted to pH 9 with NaOH and partitioned with methylene chloride. The methylene chloride phase was cleaned up through a Florisil SPE column, and residues were eluted with 2% (v:v) methanol in methylene chloride. The solvent was removed by evaporation, and residues were redissolved in ACN:water (10:90, v:v) for LC/MS/MS analysis. Residues were quantitated as the ethyl sulfone chemophore and expressed as sulfosulfuron. The statistically determined LOQ for this study was 0.0034 ppm, and the LOD was 0.0026 ppm; the validated LOQ is 0.005 ppm. This method is adequate for data collection based on acceptable concurrent recovery data.

Conclusions. The available and submitted residue analytical methods data are adequate to satisfy data requirements for purposes of the subject petition. An adequate tolerance enforcement method is available for plants, and residues of sulfosulfuron and metabolites were determined in the submitted crop field trial data using an acceptable method.

An HPLC analytical method utilizing fluorescence detection is available for enforcement purposes from ACL. The revision of the original HPLC enforcement method to use LC/MS detection resolves the previous deficiencies related to specificity and confirmatory method. These deficiencies are no longer outstanding. The LC/MS/MS method was sent to ACL for a PMV (Memo, S. Levy, 17-OCT-2006; DP#: 332807). The final decision regarding the adequacy of the revised analytical enforcement method is pending upon successful completion of a PMV by ACL.

860.1360 Multiresidue Methods

Memo, S. Chun, 28-SEP-1998; DP#: 237683
Memo, S. Chun, 30-SEP-1997; DP#: 239417

In support of the petition for use on wheat, acceptable data were submitted reflecting testing through the U.S. Food and Drug Administration (FDA) Multiresidue Methods for sulfosulfuron and its sulfonamide metabolite. Sulfosulfuron and its metabolite were not recovered using Protocol A. Sulfosulfuron appeared to degrade under the conditions used in Protocol C. Based on the results of Protocol C testing, sulfosulfuron and its metabolite were not tested through Protocols D, E, or F. The results of the multiresidue methods testing were forwarded to FDA.

860.1380 Storage Stability

Memo, S. Chun, 28-SEP-1998; DP#: 237683

Acceptable storage stability data for wheat forage and grain were submitted in support of the petition for use on wheat. The data indicated that residues of sulfosulfuron were stable in wheat grain and forage fortified with sulfosulfuron and stored frozen for up to 17.5 months.

Samples from the submitted grass field trials were stored frozen for up to 326 days (10.7 months) for grass forage and up to 300 days (9.9 months) for grass hay.

Conclusions. The available storage stability data for wheat forage are adequate to support the sample storage intervals and conditions of the submitted grass field trials.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

Memo, S. Chun, 28-SEP-1998; DP#: 237683

Grass forage and hay represent significant ruminant feed items, comprising up to ~60% of the diet for beef and dairy cattle. Because residues in/on grass forage and hay resulting from the proposed use were higher than those observed for wheat commodities, there is an appreciable increase in the anticipated MTDB for ruminants. The re-calculated MTDBs are presented below in Table 4. Grass forage and hay are not used as feed items for poultry and hog; therefore, no change to the MTDBs for poultry and hog will result from the proposed use.

Table 4. Calculation of MTDB of Sulfosulfuron Residues to Livestock.

Feedstuff	% Dry Matter[1]	% Diet[1]	Recommended Tolerance (ppm)	Dietary Contribution (ppm)[2]
Beef Cattle				
Grass, forage	25	60	14	33.6
Wheat, grain	89	25	0.02	0.006
TOTAL BURDEN	--	85[3]	--	**33.61**
Dairy Cattle				
Grass, forage	25	40	14	22.4
Wheat, grain	89	45	0.02	0.010
TOTAL BURDEN	--	85[3]	--	**22.41**
Poultry				
Wheat, grain	89	80	0.02	0.016
TOTAL BURDEN	--	80[3]	--	**0.016**
Hog				
Wheat, grain	89	80	0.02	0.016
TOTAL BURDEN	--	80[3]	--	**0.016**

[1] Table 1 (OPPTS Guideline 860.1000).

[2] Contribution = ([tolerance /% DM] X % diet) for beef and dairy cattle; contribution = ([tolerance] X % diet) for poultry and hog.

[3] The remainder of the diet will be composed of feedstuffs derived from crops that do not have sulfosulfuron uses/tolerances registered (such as peanut or cotton seed meal for cattle).

An acceptable ruminant feeding study was previously submitted and reviewed in support of the petition for use on wheat. Dairy cattle were dosed for 28 consecutive days with sulfosulfuron at levels of 8.1, 23.5, and 81.7 ppm in the diet (approximately 0.24x, 0.7x, and 2.4x the recalculated MTDBs for beef cattle; and 0.36x, 1.0x, and 3.6x the recalculated MTDBs for dairy cattle). Residues appeared to plateau in milk by Day 4, and data for all matrices were approximately linear with the dosing levels. The maximum residues of sulfosulfuron found in milk and cow tissues are listed in the Table 5 below.

Table 5. Maximum Sulfosulfuron Residues by Feeding Level from the Ruminant Feeding Study.

Matrix	Maximum Residues (ppm)		
	0.24x/0.36x[1]	0.7x/1.0x[1]	2.4x/3.6x[1]
Milk	0.004	0.019	0.034
Skim milk	≤0.003	0.009	0.024
Cream	0.005	0.006	0.012
Fat	≤0.005	0.007	0.070
Muscle	≤0.005	0.006	0.024
Kidney	0.115	0.223	1.006
Liver	0.095	0.276	0.556

[1] Beef/Dairy Cattle

A poultry feeding study has not been submitted. HED previously concluded that, due to the low residue levels in the hen metabolism study and low residue levels found in wheat grain (highest residue was 0.018 ppm), a poultry feeding study was not necessary, and tolerances for residues in poultry commodities were not required (Memo, S. Chun, 28-SEP-1998; DP# 237683).

Conclusions. Based on the results of the available feeding study and the recommended tolerances for grass forage and hay, the established tolerances for livestock commodities (*i.e.*, of cattle, goat, horse, and sheep) should be revised to 0.02 ppm for fat, 0.01 ppm for meat, 0.30 ppm for meat byproducts, and 0.02 ppm for milk.

The addition of uses on grasses does not affect the MTDB for poultry; therefore, a poultry feeding study is not required in support of this petition. Poultry feeding studies *may be required* in the future if tolerances are proposed on other crops which increase potential dietary exposure.

860.1500 Crop Field Trials

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TABLE 6. Summary of Residue Data from Crop Field Trials with Sulfosulfuron.									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring (ppm)[1]						
			n	Min.	Max.	HAFT[4]	Median	Mean	Std. Dev.
Grass Forage, Fodder, and Hay (Crop Group 17) (proposed use = 0.125 lb ai/A total application rate, 0-day PHI for forage, 14-day PHI for hay)									
Grass, forage	0.061-0.064[2]	0	26	2.95	8.53	8.41	4.59	5.00	1.58
		14	26	0.05	2.23	2.20	0.55	0.76	0.63
	0.091-0.098[3]	0	26	4.10	12.4	11.65	6.16	6.95	2.46
		14	26	0.07	3.56	3.52	0.81	1.21	0.98
	0.122-0.129[2]	0	24	1.91	11.7	11	4.68	5.16	2.6
		7	2	0.94	1.01	0.975	-	0.975	-
		14	24	0.02	5.7	5.38	0.350	1.14	1.84
		21	2	0.35	0.36	0.355	-	0.355	-
	0.123-0.129[3]	0	24	0.99	4.70	4.60	2.32	2.67	1.04
		7	2	0.50	0.54	0.52	-	0.52	-
		14	24	0.01	2.9	2.54	0.175	0.487	0.731
		21	2	0.17	0.23	0.20	-	0.20	-
Grass, hay	0.061-0.064[2]	14	14	0.16	3.38	3.17	1.49	1.47	1.11
		21	4	0.12	0.60	0.56	0.33	0.34	0.25
	0.091-0.098[3]	14	14	0.22	5.13	4.93	1.93	2.24	1.60
		21	4	0.17	1.43	1.40	0.78	0.79	0.70
	0.122-0.129[2]	14-17	18	0.24	7.23	7.14	1.11	2.80	2.72
		19-21	6	0.10	0.72	0.67	0.285	0.352	0.262
		28	2	0.54	0.62	0.58	-	0.58	-
	0.123-0.129[3]	14-17	20	0.02	3.67	3.60	0.625	0.998	1.14
		19-21	6	0.09	0.44	0.43	0.09	0.203	0.176
		28	2	0.35	0.38	0.365	-	0.365	-

[1] Residues reported as parent equivalents; note that results were not reported in this table for trials with RTIs > 56 days.
[2] Treatment 2 = 1 application at ~0.062 lb ai/A (or two applications at ~0.062 lb ai/A).
[3] Treatment 3 = 1 application at ~0.094 lb ai/A (or one application at ~0.094 lb ai/A + one application at ~0.031 lb ai/A).
[4] HAFT = Highest-Average Field Trial.

Grass Forage, Fodder, and Hay (Crop Group 17)

Monsanto Company has submitted field trial data for sulfosulfuron on grasses. Thirteen trials were conducted in the United States in Zones 1 (PA; 1 trial), 2 (GA and NC; 2 trials), 4 (AR and LA; 2 trials), 5 (IL, MI, and WI; 3 trials), 6 (TX; 1 trial), 9 (UT; 1 trial), and 11 (ID and WA; 3 trials) during the 2004 growing season. The trials consisted of four bluegrass pasture sites, five Bermudagrass pasture sites, and four sites of typical rangeland grasses. The petitioner stated that neither bromegrasses nor fescues were used in the field trials because sulfosulfuron has herbicidal activity against some bromegrasses and fescues. Instead, rangeland grass sites were selected containing grasses typical of those found in the rangeland areas for which use of sulfosulfuron is recommended.

Each field trial consisted of one untreated plot and two treated plots. At each trial plot, the 75% WDG formulation of sulfosulfuron was applied as two broadcast foliar applications for a total seasonal application rate of ~0.125 lb ai/A (1x the maximum proposed seasonal application rate). One treated plot received two applications at ~0.062 lb ai/A/application each (Treatment 2), and the other treated plot received one application at ~0.094 lb ai/A and a second application at ~0.031 lb ai/A (Treatment 3). The timing of the applications was dependent upon the type of grass and the use pattern recommended for that particular area. For pasture grasses, the first applications were made in the summer when plants were at the 6-8" growth stage, and the second applications were made 6-8 weeks later (44- to 56-day retreatment interval). For rangeland grasses, the first applications were made in the fall, and the second applications were made in the spring after the grasses started to green up. All applications were made using ground equipment in spray volumes of ~10-21 gal/A, without an adjuvant. Grass forage was collected 0 and 14 days after each application. Hay was cut 14 or 17-21 days after each application and was field dried for 1-7 days to a moisture level of 10-20%; hay was only collected after the second application at the rangeland sites. At one site (NC), additional forage samples were collected 7 and 21 days after the second application, and additional hay samples were collected 21 and 28 days after the second application, to investigate residue decline.

Samples of grass forage and hay were analyzed for residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring using a common moiety LC/MS/MS method that was adapted from the proposed enforcement method for wheat. In the method, residues of sulfosulfuron and metabolites are determined as the ethyl sulfone chemophore; residues are expressed as sulfosulfuron equivalents. The validated LOQ was 0.005 ppm. This method is adequate for data collection based on acceptable concurrent recovery data.

The maximum storage intervals of crop samples from harvest to analysis were 326 days (10.7 months) for grass forage and 300 days (9.9 months) for grass hay. Storage stability data are available (Memo, S. Chun, 28-SEP-1998; DP#: 237683) which indicate that residues of sulfosulfuron are stable under frozen storage conditions in/on fortified samples of wheat forage for up to 17.5 months. These data may be translated to grass forage and hay, and are adequate to support the storage intervals of samples from the grass field trials.

The results of the grass crop field trials are summarized in Table 6. Residues of sulfosulfuron were highest in/on grass forage collected on the day of application and declined significantly in/on forage samples harvested 14 days after each application. Residues in grass hay were typically higher than in forage harvested on the same cutting day (14-day PHI), due to residue concentration as a result of loss of plant moisture. Maximum residues were higher in/on samples of grass forage and hay harvested following Treatment 2 (two applications at ~0.062 lb ai/A) than in/on samples harvested following Treatment 3 (one application at 0.094 lb ai/A and one application at ~0.031 lb ai/A). Maximum residues in/on 0-day forage, 14-day forage, and 14-day hay were 11.00, 5.70, and 7.23 ppm, respectively, following Treatment 2, and 4.70, 2.90, and 3.67 ppm, respectively, following Treatment 3.

The results of the residue decline study indicate that residues of sulfosulfuron decline in/on grass forage and hay with increasing harvest intervals.

Conclusions. Although the representative commodities for Crop Group 17 include Bermudagrass, bluegrass, and bromegrass or fescue, the selection of rangeland grass species used in the field trials is acceptable given the herbicidal activity of sulfosulfuron on some grasses including bromegrasses and some fescues. The number and locations of field trials are in accordance with OPPTS Guideline 860.1500 for grasses.

The submitted grass crop field trial data adequately reflect the proposed use pattern with respect to application rate, timing of applications, and harvest intervals; geographic representation is adequate. Provided the petitioner amends the proposed supplemental labeling for grasses by removing directions for use of a nonionic surfactant, or provides residue data that includes use of a nonionic surfactant, the available field trial data will support tolerances for residues of sulfosulfuron and its metabolites in/on grass forage and hay.

The available field trial data will support tolerances for residues of sulfosulfuron and its metabolites in/on grass forage at 14 ppm and grass hay at 25 ppm; the tolerance calculations for grass commodities are presented in Appendix II. HED notes that the tolerance for grass forage was based on examination of residue results reflecting a single application at 0.094 lb ai/A because the highest residues observed in the field trials occurred following a single application at 0.094 lb ai/A.

860.1520 Processed Food and Feed

There are no significant processed commodities of grass, therefore, this guideline is not relevant to this petition.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for sulfosulfuron are currently available in the National Pesticide Standards Repository; however analytical standards for the ethyl sulfone chemophore metabolite of sulfosulfuron are not available (personal communication, Dynamac with D. Wright, 07-JUN-2006). **This is a deficiency.** Analytical reference standards of the ethyl sulfone metabolite should be supplied, and supplies for the analytical standards for sulfosulfuron and its ethyl sulfone metabolite should be replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Frederic Siegelman at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

860.1850/1900 Confined/Field Accumulation in Rotational Crops

Memo, S. Chun, 28-SEP-1998; DP#: 237683
Memo, S. Chun, 23-NOV-1998; DP#: 249043
Memo, P. Errico, 21-JAN-2000; No DP#

The nature of the residue in rotational crops is understood. The metabolism of sulfosulfuron in rotational crops appears to be a selective uptake of sulfosulfuron metabolites from the soil, which arise from sulfonylurea bond cleavage.

HED concluded that the residues of concern in rotational crops, for tolerance expression and risk assessment purposes, are sulfosulfuron and all metabolites which are converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine (or the ethyl sulfone chemophore).

A limited field rotational crop study (MRID 44821802) on sulfosulfuron has been submitted and reviewed to support the registration on wheat (Memo, P. Errico, 21-JAN-2000; No DP#). This study, along with a confined rotation study (MRID 44295735) showed that uptake of sulfosulfuron residues from the soil by root and tuber, leafy vegetable, and small cereal grain crops is minimal. Even with a plant-back interval (PBI) of 7 days (root/tuber crop), no residues of sulfosulfuron or its metabolites were detected above the LOD of 0.006 ppm in the field rotational crop study, when planted into soil that had been treated at 0.035 lbs ai/A. For grass pastures, the seasonal application rate is 1.2 lbs ai/A, or ~ 4 times greater than the study conditions. At the seasonal application rate, and assuming a linear application rate/residue concentration correlation, the expected residue concentrations at the higher application rate would be less than 0.024 ppm. Because the label has a 12 month minimum PBI, residues in rotational crops are not expected.

860.1550 Proposed Tolerances

Current tolerances [40 CFR §180.552] for wheat and ruminant commodities are expressed in terms of residues of sulfosulfuron and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine, calculated as sulfosulfuron.

In support of the proposed uses on grasses, the petitioner has proposed to establish tolerances for the residues of sulfosulfuron and its metabolites calculated as sulfosulfuron in/on grass forage and hay, and to revise the established tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, horses, and sheep. The established and proposed tolerances are presented in Table 7.

Adequate field trial data for grasses are available. Provided the petitioner amends the proposed supplemental labeling for grasses by removing directions for use of a nonionic surfactant, or provides residue data that includes use of a nonionic surfactant, the available field trial data will support tolerances for residues of sulfosulfuron and its metabolites in/on grass forage at 14 ppm and grass hay at 25 ppm (the tolerance calculations for grass commodities are presented in Appendix II). HED notes that the tolerance for grass forage was based on examination of residue results reflecting a single application at 0.094 lb ai/A because the highest residues observed in the field trials occurred following a single application at 0.094 lb ai/A. Because HED does not

believe this situation can be ruled out under the proposed use pattern, the tolerance for grass forage was based on the single-application data since these data yielded the highest recommended tolerance. These data indicate that the proposed tolerances of 13 ppm for grass forage and 14 ppm for grass hay are too low. The petitioner should submit a revised Section F reflecting the recommended tolerances of 14 ppm for forage and 25 ppm for hay.

In support of the proposed uses on grasses, the petitioner also proposed to revise the existing tolerances for milk, and the fat, meat, and meat byproducts of cattle, goat, horse, and sheep. An acceptable feeding study is available. Based on the available feeding study and the recommended tolerances for grass forage and hay, the proposed revised tolerances of 0.02 ppm and 0.01 ppm for milk and meat of cattle, goat, horse, and sheep are appropriate, respectively. However, the proposed tolerances of 0.03 ppm for fat and 0.4 ppm for meat byproducts are too high. The petitioner should submit a revised Section F reflecting the HED-recommended tolerances of 0.02 ppm for fat and 0.30 ppm for the meat byproducts of cattle, goat, horse, and sheep.

The proposed tolerances should be revised to reflect the correct commodity definitions as specified in Table 7. In addition, the petition should modify the proposed tolerance expression to reflect the expression stated in 40 CFR 180.552: "residues of the herbicide sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-*a*]pyridine-3-yl) sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine and calculated as sulfosulfuron."

There are no established or proposed Codex or Mexican MRLs for residues of sulfosulfuron in grasses or wheat. There are no established Canadian MRLs for residues of sulfosulfuron in grasses; a Canadian MRL has been established for sulfosulfuron residues in wheat. Therefore, there are no harmonization issues with respect to the proposed uses on grasses.

Table 7. Tolerance Summary for Sulfosulfuron.

Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Grass forage	--	13	14	*Grass, forage, fodder and hay, group 17, forage*
Grass hay	--	14	25	*Grass, forage, fodder and hay, group 17, hay*
Cattle, fat	0.005	0.03	0.02	
Cattle, meat	0.005	0.01	0.01	
Cattle, meat byproducts	0.05	0.4	0.30	
Goat, fat	0.005	0.03	0.02	
Goat, meat	0.005	0.01	0.01	
Goat, meat byproducts	0.05	0.4	0.30	
Horse, fat	0.005	0.3	0.02	
Horse, meat	0.005	0.01	0.01	
Horse, meat byproducts	0.05	0.4	0.30	
Sheep, fat	0.005	0.03	0.02	
Sheep, meat	0.005	0.01	0.01	
Sheep, meat byproducts	0.05	0.4	0.30	
Milk	0.006	0.02	0.02	

References

DP#: None
Subject: MON37500. PC Code 085601. Metabolism in Wheat.
From: L. Cheng
To: S. Irene
Date: 22-AUG-1997
MRID#: 44295707

DP#: 239417
Subject: PP# 7F04840. Multiresidue Method Testing of MON 37500 and Sulfonamide Metabolite (CP 147937).
From: S. Chun
To: F.D. Griffith
Date: 30-SEP-1997
MRID#: 44295713

DP#: 237683 and 239109
Subject: PP# 7F04840. New Chemical - Sulfosulfuron (i.e. MON37500, Maverick™) in/on Wheat. Evaluation of Residue Data and Analytical Methods. Chemical No. 085601. Case No. 288878.
From: S. Chun
To: J. Tompkins/V. Walters
Date: 28-SEP-1998
MRID#s: 44295702-04, 44295707-11, 44295713-14, 44295716-18, 44295735, 44309301

DP#: 249043
Subject: Sulfosulfuron (Maverick™) in/on Wheat. PP#7F04840. The *ad hoc* Metabolism Assessment Review Committee Meeting Held on 9/3/98. PC Code: 085601. Case #: 288878. Submission #: S526787.
From: S. Chun and A. Protzel
To: G. Kramer
Date: 23-NOV-1998
MRID#: None

DP#: 252646
Subject: PP# 7F04840. Sulfosulfuron (Maverick®) in/on Wheat RACs and Animal Commodities. Results of Petition Method Validation (PMV). Chemical No.: 085601. Case: 288878. Submission: S526787.
From: S. Chun
To: V. Walters/J. Tompkins
Date: 31-MAR-1999
MRID#: 44295710-11

DP#: 254305
Subject: PP# 7F4840. Sulfosulfuron (Maverick®) in/on Wheat RACs and Animal Commodities. Amendment of 12/3/98 and 3/3/99. PC Code: 085601. Submission #: S558623. Case #: 288878.
From: S. Chun
To: V. Walters/J. Tompkins
Date: 21-APR-1999
MRID#: None

DP#: 306356
Subject: Sulfosulfuron – Section 18 Specific Exemption for Application of Sulfosulfuron to Bermudagrass and Bahiagrass. Chronic and Cancer Dietary Exposure Assessments. PC Code: 085601.
From: T. Bloem
To: P. Shah
Date: 04-AUG-2004
MRID#: None

Attachments

Appendix I - International Residue Limit Status sheet
Appendix II - Tolerance Assessment Calculations

Template Version September 2005

Appendix I

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-*a*]pyridine-3-yl)sulfonyl]urea	Common Name: Sulfosulfuron	X Proposed tolerance Reevaluated tolerance Other	Date: 06/12/06

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above ☐No Codex proposal step 6 or above for the crops requested	PP#: 6F7031 DP#: 328450 Other Identifier:
Residue definition (step 8/CXL): N/A	Reviewer/Branch: Sarah Levy (RAB1)
	Residue definition: Sulfosulfuron and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine, calculated as sulfosulfuron

Crop(s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Grass forage	13
		Grass hay	14

Limits for Canada	Limits for Mexico
☐No Limits √No Limits for the crops requested	√No Limits ☐No Limits for the crops requested
Residue definition: *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-2-(ethylsulfonyl)imidazo[1,2-"]pyridine-3-sulfonamide and all metabolites containing theimidazopyridine moiety, expressed as sulfosulfuron	Residue definition: N/A

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions: S.Funk, Jul 10, 2006

Appendix II. Tolerance Assessment Calculations.

Grass forage

The dataset used to establish a tolerance for sulfosulfuron on forage consisted of field trial data representing a single application rate of 0.094 lb ai/A with a 0-day PHI, because the highest residues observed in the field trials occurred following a single application rate at 0.094 lb ai/A. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The residues values used to calculate the tolerance are provided below.

All 26 field trial sample results reflecting a single application rate of 0.094 lb ai/A were above the LOQ. Since there were no values reported below the LOQ, maximum likelihood estimation (MLE) procedures were not needed to impute censored values.

The sulfosulfuron-forage datasets were entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plot (Figure II-1) provided in the spreadsheet indicates that the dataset is reasonably lognormal. The result from the approximate Shapiro-Francia test statistics (Figure II-3) confirmed that the assumption of lognormality should not be rejected.

Since the field trial data for sulfosulfuron on forage harvested at a 0-day PHI with a single application rate of 0.094 lb ai/A represent a large dataset (*i.e.*, more than 15 samples) and are reasonably lognormal, the minimum of the 95% upper confidence limit (UCL) on the 95th percentile and the point estimate of the 99th percentile should be selected as the tolerance value. Using the rounding procedure as outlined in the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the 95% UCL on the 95th percentile rounds to the value 14 ppm and the point estimate of the 99th percentile rounds to the value 15 ppm (Figure II-3). Because the 14 ppm value was the minimum value, 14 ppm would be the recommended tolerance level for sulfosulfuron on 0-day forage following a single application rate of 0.094 lb ai/A.

HED concludes that 14 ppm is the appropriate tolerance level for sulfosulfuron on 0-day forage harvested following a single application rate of 0.094 lb ai/A.

Grass hay

The dataset used to establish a tolerance for sulfosulfuron on hay consisted of field trial data representing a total application rate of 0.125 lb ai/A (two applications at ~0.062 lb ai/A/application each with a ~14-day PHI. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The residues values used to calculate the tolerance are provided below.

All 18 field trial sample results were above the LOQ. Since there were no values reported below the LOQ, MLE procedures were not needed to impute censored values.

The sulfosulfuron-forage dataset was entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plot (Figure II-2) provided in the spreadsheet indicates that the dataset

is reasonably lognormal. The result from the approximate Shapiro-Francia test statistic (Figure II-4) confirmed that the assumption of lognormality should not be rejected.

Since the field trial data for sulfosulfuron on hay represent a large dataset (*i.e.*, more than 15 samples) and are reasonably lognormal, the minimum of the 95% UCL on the 95th percentile and the point estimate of the 99th percentile should be selected as the tolerance value. Using the rounding procedure as outlined in the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the 95% UCL on the 95th percentile rounds to the value 30 ppm and the point estimate of the 99th percentile rounds to the value 25 ppm (Figure II-4). Because the 25 ppm value was the minimum value, 25 ppm is the recommended tolerance level for sulfosulfuron on grass hay.

HED concludes that 25 ppm is the appropriate tolerance level for sulfosulfuron representing a total application rate of 0.125 lb ai/A (two applications at ~0.062 lb ai/A/application each with a ~14-day PHI).

Regulator:	EPA	
Chemical:	Sulfosulfuron	
Crop:	Grass forage	Grass hay
PHI:	0	14-17 Days
Application Rate:	1 at 0.094 ai/A	1.25 lb ai/A
Submitter:	Monsanto	
MRID#:	46573801	
Combined residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring (ppm)		
	4.79	1.80
	5.16	1.91
	9.67	5.63
	12.40	5.68
	4.64	0.83
	4.78	0.89
	5.76	6.21
	6.50	6.95
	4.10	1.03
	4.35	1.19
	6.03	0.24
	6.59	0.26
	4.44	7.04
	4.46	7.23
	5.74	0.90
	6.12	0.91
	6.97	0.79
	7.90	0.90
	9.54	
	10.10	
	11.40	
	11.90	
	7.32	
	7.84	
	6.15	
	6.17	

Figure II- 1. Lognormal probability plot of sulfosulfuron field trial data for forage (one application at 0.094 lb ai/A).

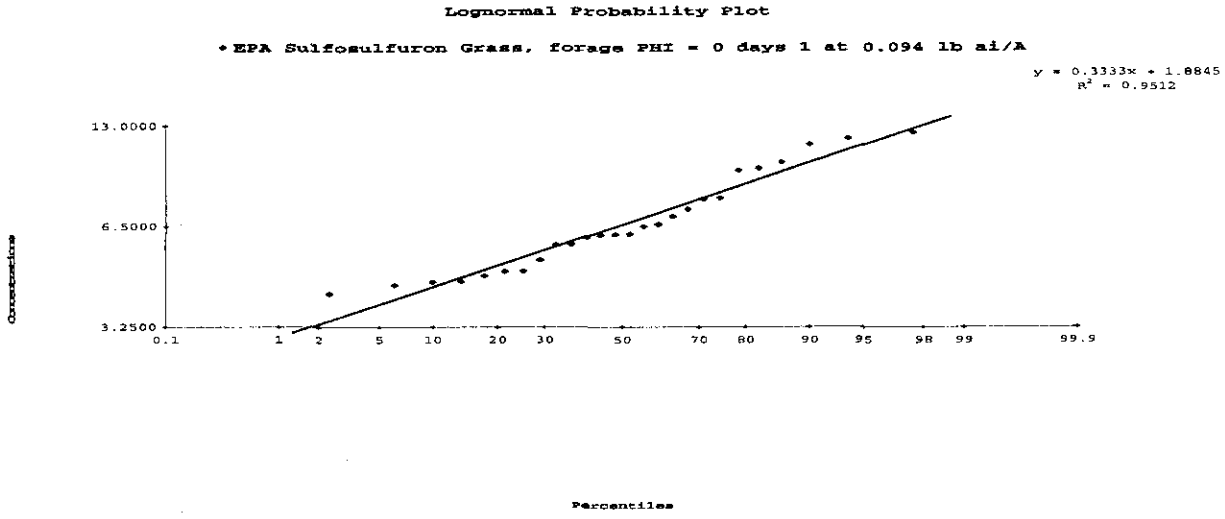


Figure II- 2. Lognormal probability plot of sulfosulfuron field trial data for hay (2 applications at 0.062 lb ai/A).

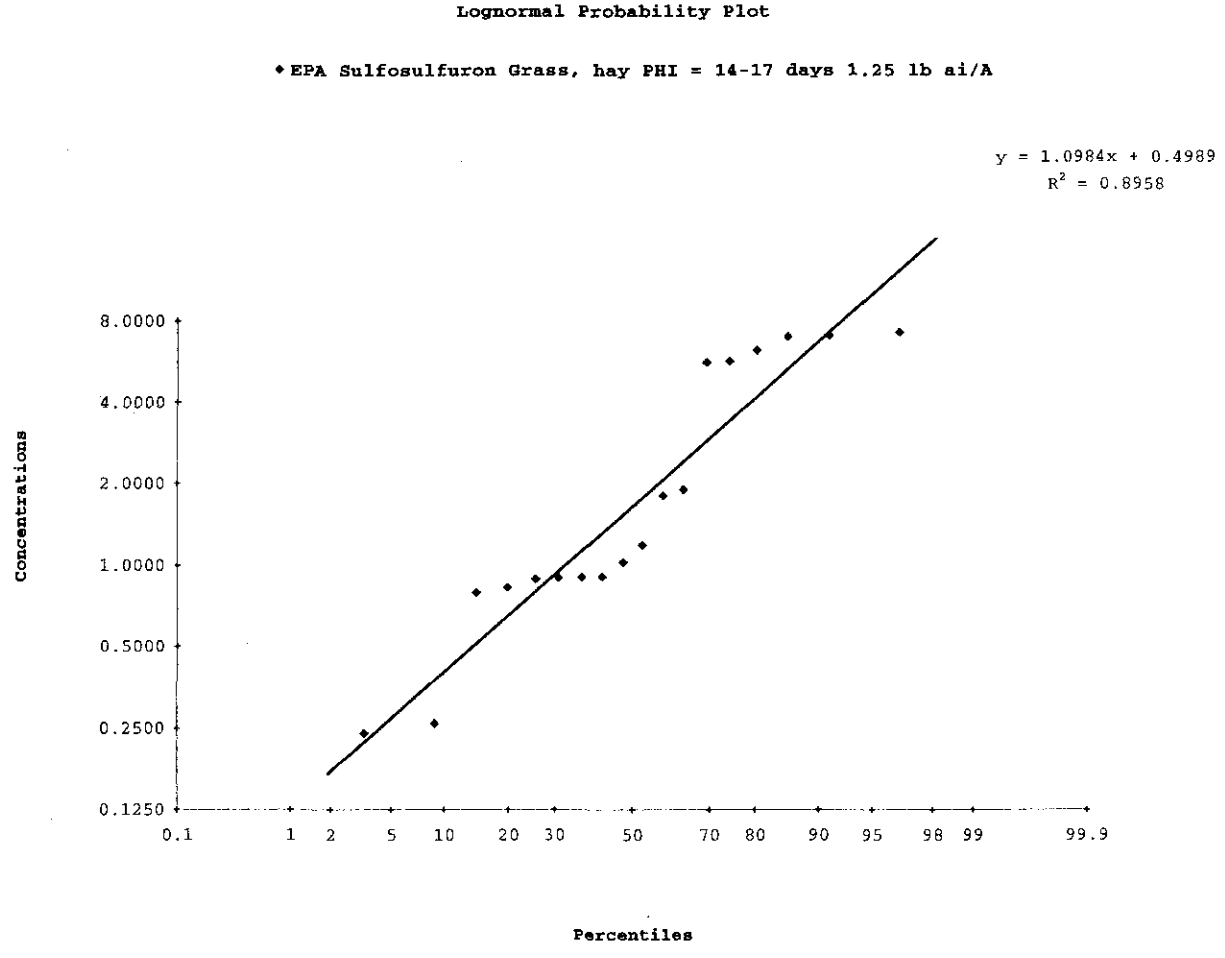


Figure II- 3. Tolerance spreadsheet summary of sulfosulfuron field trial data for forage (1 application at 0.094 lb ai/A).

	Regulator:	EPA	
	Chemical:	Sulfosulfuron	
	Crop:	Grass, forage	
	PHI:	PHI = 0 days	
	App. Rate:	1 at 0.094 lb ai/A	
	Submitter:		
	n:	26	
	min:	4.10	
	max:	12.40	
	median:	6.16	
	average:	6.95	
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I	11	13	15
Normal	(13)	(15)	(--)
EU Method I	12	15	19
Log Normal	(18)	(19)	(--)
EU Method II		17	
Distribution-Free			
California Method		15	
μ + 3σ			
UPLMedian95th		40	
Approximate		0.9512	
Shapiro-Francia	p-value > 0.05 : Do not reject lognormality assumption		
Normality Test			
Would you like the above values round		Y	

Figure II-4. Tolerance spreadsheet summary of sulfosulfuron field trial data for hay (2 applications at 0.062 lb ai/A)

	Regulator:	EPA	
	Chemical:	Sulfosulfuron	
	Crop:	Grass, hay	
	PHI:	PHI = 14-17 days	
	App. Rate:	1.25 lb ai/A	
	Submitter:		
	n:	18	
	min:	0.24	
	max:	7.23	
	median:	1.11	
	average:	2.80	
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I	8.0	10	12
Normal	(10)	(12)	(--)
EU Method I	11	26	55
Log Normal	(30)	(75)	(--)
EU Method II		12	
Distribution-Free			
California Method		11	
μ + 3σ			
UPLMedian95th		8.0	
Approximate		0.8958	
Shapiro-Francia	p-value > 0.05 : Do not reject lognormality assumption		
Normality Test			
Would you like the above values round		Y	

Primary Evaluator: Date: 25-JUL-2007
Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED; 7509P)

Approved by: Date: 25-JUL-2007
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 12-JUL-2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46753801. Moran, S. (2005) Magnitude of the Residues of Sulfosulfuron and Its Metabolites in Grasses From Pastures and Rangelands After Treatment with MON 37503. Project Number: 04/13/R/1, MSL/19348, 1661. Unpublished study prepared by Carringers, Inc., Monsanto Company and Agricultural Systems Associates. 283 p.

EXECUTIVE SUMMARY:

Monsanto Company has submitted field trial data for sulfosulfuron on grasses. Thirteen trials were conducted in the United States in Zones 1 (PA; 1 trial), 2 (GA and NC; 2 trials), 4 (AR and LA; 2 trials), 5 (IL, MI, and WI; 3 trials), 6 (TX; 1 trial), 9 (UT; 1 trial), and 11 (ID and WA; 3 trials) during the 2004 growing season. The trials consisted of four Bluegrass pasture sites, five Bermudagrass pasture sites, and four sites of typical rangeland grasses. The petitioner stated that neither bromegrasses nor fescues were used in the field trials because sulfosulfuron has herbicidal activity against some bromegrasses and fescues. Instead, rangeland grass sites were selected containing grasses typical of those found in the rangeland areas for which use of sulfosulfuron is recommended.

Each field trial consisted of one untreated plot and two treated plots. At each trial plot, the 75% water-dispersible granule (WDG) formulation of sulfosulfuron was applied as two broadcast foliar applications for a total seasonal application rate of ~0.125 pounds active ingredient per acre (lb ai/A). One treated plot received two applications at ~0.062 lb ai/A/application each (Treatment 2), and the other treated plot received one application at ~0.094 lb ai/A and a second application at ~0.031 lb ai/A (Treatment 3). The timing of the applications was dependent upon the type of grass and the use pattern recommended for that particular area. For pasture grasses, the first applications were made in the summer when plants were at the 6-8" growth stage, and the second applications were made 6-8 weeks later (44- to 56-day retreatment interval (RTI)). For rangeland grasses, the first applications were made in the fall, and the second applications were made in the spring after the grasses started to green up. All applications were made using

ground equipment in spray volumes of ~10-21 gal/A, without an adjuvant. Grass forage was collected 0 and 14 days after each application. Hay was cut 14 or 17-21 days after each application and was field dried for 1-7 days to a moisture level of 10-20%; hay was only collected after the second application at the rangeland sites. At one site (NC), additional forage samples were collected 7 and 21 days after the second application, and additional hay samples were collected 21 and 28 days after the second application, to investigate residue decline.

Samples of grass forage and hay were analyzed for residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring using a common moiety liquid chromatograph/mass spectrometry/mass spectrometry (LC/MS/MS) method that was adapted from the proposed enforcement method for wheat. In the method, residues of sulfosulfuron and metabolites are determined as the ethyl sulfone chemophore; residues are expressed as sulfosulfuron equivalents. The validated limit of quantitation (LOQ) was 0.005 ppm. This method is adequate for data collection based on acceptable concurrent recovery data.

The maximum storage intervals of crop samples from harvest to analysis were 326 days (10.7 months) for grass forage and 300 days (9.9 months) for grass hay. Storage stability data are available (Memo, S. Chun, 28-SEP-1998; DP#: 237683) which indicate that residues of sulfosulfuron are stable under frozen storage conditions in/on fortified samples of wheat forage for up to 17.5 months. These data may be translated to grass forage and hay, and are adequate to support the storage intervals of samples from the grass field trials.

The maximum sulfosulfuron residues in/on pasture and rangeland grass forage and hay from the submitted grass field trials are reported below.

Maximum Sulfosulfuron Residues in/on Grass Forage and Hay Following Application of the 75% WDG Formulation[1].

Commodity	Total Applic. Rate (lb ai/A)	PHI[2] (days)	*Maximum Residue Levels* (ppm, sulfosulfuron equivalents)
Grass, forage	0.061-0.064[3]	0	8.53
		14	2.23
	0.091-0.098[4]	0	12.4
		14	3.56
	0.122-0.129[3]	0-7	11.7
		14-21	5.7
	0.123-0.129[4]	0-7	4.7
		14-21	2.9
Grass, hay	0.061-0.064[3]	14	3.38
		21	0.60
	0.091-0.098[4]	14	5.13
		21	1.43
	0.122-0.129[3]	14-17	7.23
		19-28	0.72
	0.123-0.129[4]	14-17	3.67
		19-28	0.44

[1] Residues reported as parent equivalents.
[2] PHI = pre-harvest interval.
[3] Treatment 2 = two applications at ~0.062 lb ai/A.
[4] Treatment 3 = one application at ~0.094 lb ai/A + one application at ~0.031 lb ai/A.

The highest residue observed in forage was 12.4 ppm, after a single application rate of 0.094 lb ai/A (Treatment 3), and PHI of 0-days. The highest residue observed in hay was 7.23 ppm, after a total application rate of 0.127 lb ai/A (Treatment 2), and a PHI of 14 days.

The results of the residue decline study indicate that sulfosulfuron residues decline in grass forage and hay with increasing pre-harvest intervals following treatment at a total application rate of 0.122-0.129 lb ai/A. In forage, after a total application rate of 0.122-0.129 lb ai/A (Treatment 2), average residues declined from 5.16 ppm to 0.355 ppm, and after a total application rate of 0.123-0.129 lb ai/A (Treatment 3), average residues declined from 2.67 ppm to 0.20 ppm In hay, after a total application rate of 0.122-0.129 lb ai/A (Treatment 2), average residues declined from 2.53 ppm to 0.58 ppm, and after a total application rate of 0.123-0.129 lb ai/A (Treatment 3), average residues declined from 0.998 ppm to 0.365 ppm

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the grass field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 328450.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Sulfosulfuron is a selective broadleaf sulfonylurea herbicide currently registered for control of grass and broadleaf weeds in spring and winter wheat. Sulfosulfuron exhibits systemic postemergence herbicidal activity on a broad spectrum of annual and perennial sedges, grasses, and broadleaf weeds, but does not injure many warm-season and some cool-season grasses.

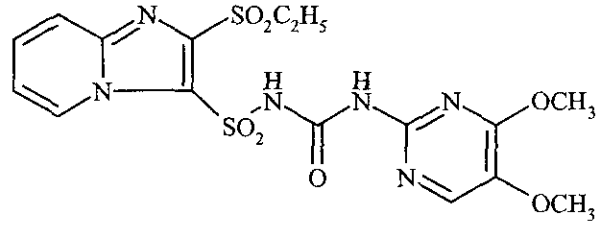
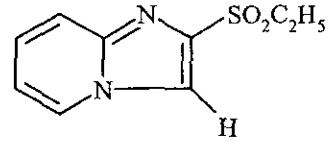
TABLE A.1. Sulfosulfuron Nomenclature.	
Chemical structure	
Common name	Sulfosulfuron
Company experimental name	MON 37500; TKM-19
IUPAC name	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-ethylsulfonylimidazo[1,2-*a*]pyridin-3-ylsulfonyl)urea
CAS name	*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-2-(ethylsulfonyl)imidazo[1,2-*a*]pyridine-3-sulfonamide
CAS registry number	141776-32-1
End-use product (EP)	75% WDG (Maverick® Herbicide; EPA Reg. No. 524-500)
Chemical structure of ethyl sulfone chemophore	 2-(ethylsulfonyl)-imidazo [1,2-a]pyridine

TABLE A.2. Physicochemical Properties of Sulfosulfuron Technical Grade of the Active Ingredient.		
Parameter	Value	Reference
Melting range	180.9-184.1°C	MRID 44295704; Memo, S. Chun, 28-SEP-1998; DP#: 237683
pH	4.76	
Density	1.55 g/mL at 20°C	
Water solubility	ppm at 20°C pH 5: 17.60 ± 2.71 pH 7: 1626.8 ± 39.8 pH 9: 482.44 ± 8.35	
Solvent solubility	ppm at 20°C Heptane: <1 Xylene: 160 Methanol: 330 Ethyl acetate: 1010 Dichloroethane: 4350	
Vapor pressure	2.29×10^{-10} mm Hg at 20°C 6.61×10^{-10} mm Hg at 25°C	
Dissociation constant, pK_a	pK_a = 3.51 at 20°C	
Octanol/water partition coefficient, Log(K_{OW})	pH 5: K_{OW} = 6.38; pK_{OW} = 0.81 pH 7: K_{OW} = 0.14; pK_{OW} = -1.01 pH 9: K_{OW} = 0.036; pK_{OW} = -1.37	
UV/visible absorption spectrum	UV_{MAX} = 208 nm ε = 187,150 L/mol cm (pH >10.0, 1.06% by weight in water, 26°C)	

B. EXPERIMENTAL DESIGN

Thirteen grass field trials were conducted in the United States in Zones 1 (PA; 1 trial), 2 (GA and NC; 2 trials), 4 (AR and LA; 2 trials), 5 (IL, MI, and WI; 3 trials), 6 (TX; 1 trial), 9 (UT; 1 trial), and 11 (ID and WA; 3 trials) during the 2004 growing season. The trials consisted of four Bluegrass pasture sites, five Bermudagrass pasture sites, and four sites of typical rangeland grasses.

Each field trial consisted of one untreated plot and two treated plots. At each trial plot, the 75% WDG formulation of sulfosulfuron was applied as two broadcast foliar applications for a total seasonal application rate of ~0.125 lb ai/A. The study use pattern is detailed in Table B.1.2. One treated plot received two applications at ~0.062 lb ai/A/application each (Treatment 2), and the other treated plot received one application at ~0.094 lb ai/A and a second application at ~0.031 lb ai/A (Treatment 3). The timing of the applications was dependent upon the type of grass and the use pattern recommended for that particular area. For pasture grasses, the first applications were made in the summer when plants were at the 6-8" growth stage, and the second applications were made 6-8 weeks later (44- to 56-day RTIs). For rangeland grasses, the first applications were made in the fall, and the second applications were made in the spring, after the grasses started to green up. The spring application was not made at the second ID rangeland grass site because of severe damage that was apparently caused by fall application of pronamide as a maintenance chemical. All applications were made using ground equipment in spray volumes of ~10-21 gal/A, without an adjuvant.

To insure good growth of the test crops and that treatments were made according to normal agronomic practices, applications were applied when rainfall was expected within the next few days to encourage growth of the grasses; supplemental irrigation was used if necessary. Maintenance chemicals and pesticides were applied as needed. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C.3. Average minimum and maximum temperatures and total precipitation for the study period were reported, along with the average 10-year historical data. In general, temperatures and rainfall were normal at all trial sites. The registrant stated that the test crops were not adversely affected by climatic conditions at any site.

Phytotoxicity (stunting and/or discoloration) was observed after all applications at the Bluegrass pasture sites (PA, MI, and WI), and some stunting was observed following the second applications at the rangeland grass site at American Falls, ID, but phytotoxicity at these sites did not prevent collection of sufficient samples. Treatment-related phytotoxicity following the second applications resulted in collection of smaller than specified samples at the UT rangeland grass site; however, sample sizes were still sufficient for analysis.

Grass forage was collected 0 and 14 days after each application. Hay was cut 14 or 17-21 days after each application and was field dried for 1-7 days to a moisture level of 10-20%; hay was only collected after the second application at the rangeland sites. At one trial (NC), additional forage samples were collected 7 and 21 days after the second application, and additional hay samples were collected 21 and 28 days after the second application, to investigate residue decline.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial ID #)	Soil characteristics[1]			
	Type	%OM	pH	CEC
Germansville, PA; 2004 (04-13-R-1-PA)	Loam	Not Provided.		
Conklin, MI; 2004 (04-13-R-1-MI)	Loam			
Delavan, WI; 2004 (04-13-R-1-WI)	Silt loam			
Carlyle, IL; 2004 (04-13-R-1-IL)	Silt loam			
Magnolia, NC; 2004 (04-13-R-1-NC)	Loamy sand			
Chula, GA; 2004 (04-13-R-1-GA)	Loamy sand			
Swifton, AR; 2004 (04-13-R-1-AR)	Fine sandy loam			
Washington, LA; 2004 (04-13-R-1-LA)	Silt loam			
Brookshire, TX; 2004 (04-13-R-1-TX)	Sandy loam			
Ephrata, WA; 2004 (04-13-R-1-WA)	Sandy loam			
American Falls, ID; 2004 (04-13-R-1-ID-1)	loam			
Fruitland, ID; 2004 (04-13-R-1-ID-2)	Silt loam			
Logan, UT; 2004 (04-13-R-1-UT)	Silty clay			

[1] %OM = percent of organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Location: City, State; Year (Trial ID #)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment	Method; Timing	Volume[2] (GPA)	Rate (lb ai/A)	RTI[3] (days)	Total Rate (lb ai/A)	
Germansville, PA; 2004 (04-13-R-1-PA)	75% WDG	2	1. Broadcast foliar; vegetative, 6-8" crop height	18.8	0.064	--	0.128	None
			2. Broadcast foliar; vegetative, 6-10" crop height	19.0	0.064	46		
	75% WDG	3	1. Broadcast foliar; vegetative, 6-8" crop height	19.1	0.097	--	0.128	
			2. Broadcast foliar; vegetative, 6-10" crop height	18.8	0.031	46		
Conklin, MI; 2004 (04-13-R-1-MI)	75% WDG	2	1. Broadcast foliar; 3-4 leaves, 6-8" crop height	16.7	0.062	--	0.124	None
			2. Broadcast foliar; 2-3 leaves, 9-13" crop height	15.9	0.062	48		
	75% WDG	3	1. Broadcast foliar; 3-4 leaves, 6-8" crop height	16.8	0.094	--	0.125	
			2. Broadcast foliar; 2-3 leaves, 9-13" crop height	16.0	0.031	48		
Delavan, WI; 2004 (04-13-R-1-WI)	75% WDG	2	1. Broadcast foliar; vegetative, 8-12" crop height	17.9	0.061	--	0.125	None
			2. Broadcast foliar; vegetative, 6-12" crop height	18.8	0.064	54		
	75% WDG	3	1. Broadcast foliar; vegetative, 8-12" crop height	18.0	0.093	--	0.125	
			2. Broadcast foliar; vegetative, 6-12" crop height	18.5	0.031	54		
Carlyle, IL; 2004 (04-13-R-1-IL)	75% WDG	2	1. Broadcast foliar; vegetative, 7-8" crop height	10.9	0.061	--	0.126	None
			2. Broadcast foliar; vegetative, 10-12" crop height	10.1	0.065	54		
	75% WDG	3	1. Broadcast foliar; vegetative, 7-8" crop height	10.8	0.092	--	0.123	
			2. Broadcast foliar; vegetative, 10-12" crop height	9.9	0.031	54		
Magnolia, NC; 2004 (04-13-R-1-NC)	75% WDG	2	1. Broadcast foliar; early regrowth, 6-8" crop height	12.4	0.061	--	0.122	None
			2. Broadcast foliar; forage, 8-10" crop height	17.9	0.061	44		
	75% WDG	3	1. Broadcast foliar; early regrowth, 6-8" crop height	12.4	0.091	--	0.123	
			2. Broadcast foliar; forage, 8-10" crop height	18.4	0.031	44		
Chula, GA; 2004 (04-13-R-1-GA)	75% WDG	2	1. Broadcast foliar; prior to boot stage, 6-8" crop height	14.7	0.064	--	0.129	None
			2. Broadcast foliar; early boot stage, 10-12" crop height	13.8	0.065	51		

TABLE B.1.2. Study Use Pattern.

Location: City, State; Year (Trial ID #)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment	Method; Timing	Volume[2] (GPA)	Rate (lb ai/A)	RTI[3] (days)	Total Rate (lb ai/A)	
	75% WDG	3	1. Broadcast foliar; prior to boot stage, 6-8" crop height	14.5	0.096	--	0.126	
			2. Broadcast foliar; early boot stage, 10-12" crop height	13.8	0.030	51		
Swifton, AR; 2004 (04-13-R-1-AR)	75% WDG	2	1. Broadcast foliar; BBCH 34-37, 6-8" crop height	20.2	0.063	--	0.127	None
			2. Broadcast foliar; BBCH 34-37, 6-8" crop height	20.2	0.063	44		
	75% WDG	3	1. Broadcast foliar; BBCH 34-37, 6-8" crop height	20.2	0.093	--	0.123	
			2. Broadcast foliar; BBCH 34-37, 6-8" crop height	19.9	0.030	44		
Washington, LA; 2004 (04-13-R-1-LA)	75% WDG	2	1. Broadcast foliar; pre-boot, 6-8" crop height	12.4	0.063	--	0.125	None
			2. Broadcast foliar; heading, 6-8" crop height	17.6	0.062	47		
	75% WDG	3	1. Broadcast foliar; pre-boot, 6-8" crop height	12.4	0.094	--	0.125	
			2. Broadcast foliar; heading, 6-8" crop height	17.6	0.031	47		
Brookshire, TX; 2004 (04-13-R-1-TX)	75% WDG	2	1. Broadcast foliar; vegetative, 6-8" crop height	19.2	0.063	--	0.127	None
			2. Broadcast foliar; boot to early heading, 6-8" crop height	18.8	0.063	56		
	75% WDG	3	1. Broadcast foliar; vegetative, 6-8" crop height	19.2	0.095	--	0.126	
			2. Broadcast foliar; boot to early heading, 6-8" crop height	19.0	0.031	56		
Ephrata, WA; 2004 (04-13-R-1-WA)	75% WDG	2	1. Broadcast foliar; prior to stem elongation, 6-8" crop height	15.2	0.062	--	0.125	None
			2. Broadcast foliar; past green up, 4-6" crop height	14.9	0.063	231		
	75% WDG	3	1. Broadcast foliar; prior to stem elongation, 6-8" crop height	15.3	0.094	--	0.125	
			2. Broadcast foliar; past green up, 4-6" crop height	14.8	0.031	231		
American Falls, ID; 2004 (04-13-R-1-ID-1)	75% WDG	2	1. Broadcast foliar; fall regrowth, 10-16" crop height	18.2	0.063	--	0.125	None
			2. Broadcast foliar; spring growth, 8-14" crop height	18.1	0.062	225		
	75% WDG	3	1. Broadcast foliar; fall regrowth, 10-16" crop height	18.5	0.098	--	0.129	
			2. Broadcast foliar; spring growth, 8-14" crop height	18.1	0.031	225		

TABLE B.1.2. Study Use Pattern.

Location: City, State; Year (Trial ID #)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment	Method; Timing	Volume[2] (GPA)	Rate (lb ai/A)	RTI[3] (days)	Total Rate (lb ai/A)	
Fruitland, ID[4]; 2004 (04-13-R-1-ID-2)	75% WDG	2	1. Broadcast foliar; vegetative, 6-8" crop height	19.6	0.061	--	0.061	None
	75% WDG		1. Broadcast foliar; vegetative, 6-8" crop height	20.0	0.094	--	0.094	
Logan, UT; 2004 (04-13-R-1-UT)	75% WDG	2	1. Broadcast foliar; fall regrowth, 8-15" crop height	18.1	0.062	--	0.124	None
			2. Broadcast foliar; spring growth, 3-12" crop height	18.1	0.061	224		
	75% WDG	3	1. Broadcast foliar; fall regrowth, 8-15" crop height	18.1	0.097	--	0.127	
			2. Broadcast foliar; spring growth, 3-12" crop height	18.1	0.030	224		

[1] EP = End-use Product.
[2] GPA = gallons per acre.
[3] RTI = Retreatment Interval.
[4] Second applications were not made at this site because of the poor grass stand.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Grasses		
	Submitted	Requested	
		Canada	U.S.
1	1 (Bluegrass)		
2	2 (Bermudagrass)		
4	2 (Bermudagrass)		
5	3 (Bluegrass)		
6	1 (Bermudagrass)		
9	1 (rangeland grass)		
11	3 (rangeland grass)		
Total	13		12[1]

[1] OPPTS 860.1500, Tables 2 and 5 require 4 trials for each of 3 grass cultivars (Bermudagrass, Bluegrass, and bromegrass or fescue) for a total of 12 trials, conducted in all areas across the country.

B.2. Sample Handling and Preparation

Grass forage and hay samples were cut using various manual and mechanical clippers; hay samples were field dried for 1-7 days prior to collection. Forage and hay samples were placed in frozen storage (-37 to -6 °C) within 4 hours of collection and were shipped frozen to Monsanto Company, Environmental Sciences Technology Center (St. Louis, MO) for residue analysis within 1-67 days of harvest. Samples were stored frozen (<-10 °C) at the analytical laboratory until homogenization (grinding with dry ice) and analysis.

B.3. Analytical Methodology

Samples of grass forage and hay were analyzed for residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring using a common moiety LC/MS/MS method that was adapted from the proposed enforcement method for wheat. In the method, residues of sulfosulfuron and its metabolites are hydrolyzed to the ethyl sulfone chemophore. Modifications included use of LC/MS/MS analysis instead of high-performance liquid chromatography (HPLC) with fluorescence detection and elimination of the amino solid-phase extraction (SPE) cleanup step. A description and a copy of the modified method were included with the submission.

Briefly, homogenized samples were extracted with acetonitrile (ACN):water (1:1, v:v). The extract was filtered, concentrated, and refluxed with HCl overnight. The hydrolyzed extract was adjusted to pH 9 with NaOH and partitioned with methylene chloride. The methylene chloride phase was cleaned up through a Florisil SPE column, and residues were eluted with 2% (v:v) methanol in methylene chloride. The solvent was removed by evaporation, and residues were redissolved in ACN:water (10:90, v:v) for LC/MS/MS analysis. Residues were quantitated as the ethyl sulfone chemophore and expressed as sulfosulfuron. The statistically determined LOQ for this study was 0.0034 ppm, and the limit of detection (LOD) was 0.0026 ppm; the validated LOQ is 0.005 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage interval of crop samples from harvest to analysis was 326 days (10.7 months) for grass forage and 300 days (9.9 months) for grass hay. Storage stability data are available (Memo, S. Chun, 28-SEP-1998; DP#: 237683) which indicate that residues of sulfosulfuron are stable under frozen storage conditions in/on fortified samples of wheat forage for up to 17.5 months. These data may be translated to grass forage and hay, and are adequate to support the storage intervals of samples from the grass field trials.

Concurrent recovery data are presented in Table C.1. Samples of grass forage and hay were analyzed for residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring using a common moiety LC/MS/MS method that was adapted from the proposed enforcement method for wheat. In the method, residues of sulfosulfuron and metabolites are determined as the ethyl sulfone chemophore; residues are expressed as sulfosulfuron equivalents. The validated LOQ was 0.005 ppm and the LOD was ~0.003 ppm. This method is adequate for data collection based on acceptable concurrent recovery data. Overall concurrent recoveries ranged 64-115% (mean = 97 ± 11%) for grass forage fortified at 0.005-20 ppm, and 81-113% (mean = 95 ± 11%) for grass hay fortified at 0.005-50 ppm. Sample chromatograms were supplied which indicated that the matrix was relatively free of interferences; apparent residues of sulfosulfuron were nondetectable (reported as 0 ppm) in/on all samples of untreated grass forage and hay.

The results of the pasture and rangeland grass field trials are reported in Table C.3. A summary of the residue data is presented in Table C.4. Sulfosulfuron residues were highest in grass forage collected on the day of application, and declined significantly in/on forage harvested 14 days after each application. In 0-day grass forage, sulfosulfuron residues ranged 2.95-8.53 ppm following a single foliar broadcast application of the 75% WDG formulation at 0.061-0.064 lb ai/A and 4.10-12.4 ppm following a single application at 0.091-0.098 lb ai/A. In 0-day grass forage, sulfosulfuron residues ranged 1.91-11.7 ppm following two applications of the 75% WDG formulation totaling 0.122-0.129 lb ai/A (Treatment 2) and 0.99-4.70 ppm following two applications totaling 0.123-0.129 lb ai/A (Treatment 3). In 14-day grass forage, residues ranged 0.05-2.23 ppm following a single application at 0.061-0.064 lb ai/A and 0.07-3.56 ppm following a single application at 0.091-0.098 lb ai/A. In 14-day grass forage, sulfosulfuron residues ranged 0.02-5.7 ppm following two applications of the 75% WDG formulation totaling 0.122-0.129 lb ai/A (Treatment 2) and 0.01-2.9 ppm following two applications totaling 0.123-0.129 lb ai/A (Treatment 3).

Residues in grass hay were typically higher than in forage harvested on the same cutting day (14-day PHI), due to residue concentration by the loss of plant moisture. In hay cut 14 days after application, residues of sulfosulfuron ranged 0.16-3.38 ppm following a single application at 0.061-0.64 lb ai/A and 0.22-5.13 ppm following a single application at 0.091-0.098 lb ai/A. In hay cut 14-17 days after application, residues of sulfosulfuron ranged 0.06-7.23 ppm following two applications totaling 0.122-0.129 lb ai/A (Treatment 2) and 0.02-3.67 ppm following two applications totaling 0.123-0.129 lb ai/A (Treatment 3). In hay cut 21 days after application, residues of sulfosulfuron ranged 0.12-0.60 ppm following a single application at 0.061-0.64 lb ai/A and 0.17-1.43 ppm following a single application at 0.091-0.098 lb ai/A. In hay cut 19-28 days after application, residues ranged 0.10-0.72 ppm following two applications totaling 0.122-0.129 lb ai/A (Treatment 2) and 0.09-0.44 ppm following two applications totaling 0.123-0.129 lb ai/A (Treatment 3).

The highest residue observed in forage was 12.4 ppm, after a single application rate of 0.094 lb ai/A (Treatment 3), and PHI of 0-days. The highest residue observed in hay was 7.23 ppm, after a total application rate of 0.127 lb ai/A (Treatment 2), and a PHI of 14 days.

The results of the residue decline study indicate that sulfosulfuron residues decline in grass forage and hay with increasing pre-harvest intervals following treatment at a total application rate of 0.122-0.129 lb ai/A. In forage, after a total application rate of 0.122-0.129 lb ai/A (Treatment 2), average residues declined from 5.16 ppm to 0.355 ppm, and after a total application rate of 0.123-0.129 lb ai/A (Treatment 3), average residues declined from 2.67 ppm to 0.20 ppm In hay, after a total application rate of 0.122-0.129 lb ai/A (Treatment 2), average residues declined from 2.53 ppm to 0.58 ppm, and after a total application rate of 0.123-0.129 lb ai/A (Treatment 3), average residues declined from 0.998 ppm to 0.365 ppm

TABLE C.1. Summary of Concurrent Recoveries of Sulfosulfuron from Grass Matrices.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev[1] (%)
Grass, forage	0.005	5	63.6, 93.2, 93.2, 97.0, 99.6	89.3 ± 14.6
	0.010	4	80.8, 81.0, 90.0, 106	89.5 ± 11.8
	0.020	4	90.0, 90.3, 92.5, 92.9	91.4 ± 1.5
	0.050	3	69.4, 77.2, 99.1	81.9 ± 15.4
	0.100	3	89.8, 96.8, 112	99.5 ± 11.3
	0.200	5	98.4, 103, 105, 107, 111	105 ± 4.7
	0.500	5	82.4, 99.4, 100, 102, 113	99.4 ± 11.0
	1.00	5	92.2, 95.5, 98.3, 98.5, 109	98.7 ± 6.3
	2.00	6	90.0, 93.5, 96.0, 101, 107, 113	100 ± 8.7
	5.00	5	98.0, 100, 107, 108, 115	106 ± 6.8
	10.0	7	88.7, 93.9, 99.2, 103, 104, 105, 112	101 ± 7.7
	20.0	2	98.5, 104	101
Grass, hay	0.005	2	81.3, 84.9	83.1
	0.010	2	82.7, 87.8	85.3
	0.020	3	82.9, 84.5, 88.4	85.3 ± 2.8
	0.050	3	92.6, 96.0, 110	99.5 ± 9.2
	0.100	3	81.5, 85.6, 90.8	86.0 ± 4.7
	0.200	1	94.3	94.3
	0.500	1	109	109
	1.00	1	110	110
	2.00	2	107, 109	108
	5.00	1	113	113
	10.0	1	96.0	96.0
	20.0	1	99.0	99.0
	50.0	2	106, 110	108

[1] Mean and standard deviations were calculated by the study reviewer; standard deviations were not calculated for fortification levels with <3 recovery values.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Grass, forage	< -10	49-326 days (1.6-10.7 months)	Stable in/on fortified wheat forage stored frozen for up to 531 days (17.5 months).[2]
Grass, hay		75-300 days (2.5-9.9 months)	

[1] Interval from harvest (cutting for hay) to analysis; all samples were analyzed within 5-24 days of extraction.
[2] Refer to Memo, S. Chun, 28-SEP-1998; DP#: 237683.

TABLE C.3. Residue Data from Grass Field Trials with Sulfosulfuron.

Trial ID: City, State; Year (Trial ID #)	Zone	Crop; Variety	Treatment[1]	Total Rate (lb ai/A)	Commodity or Matrix	PHI[2] (days)	Residues[3] (ppm sulfosulfuron equivalents)
Germansville, PA; 2004 (04-13-R-1-PA)	1	Bluegrass; 10% Touchdown, 20% Merrit, 20% Classic, 20% Destiny, 30% Gnome	2	0.064	forage	0	4.35, 4.50
						14	0.45, 0.49
					hay	21 (6)	0.51, 0.60
				0.128	forage	0	5.60[4], 6.25[4]
						14	0.89, 0.96
					hay	17 (5)	1.80, 1.91
			3	0.097	forage	0	4.79, 5.16[4]
						14	0.66, 0.75
					hay	21 (6)	1.36, 1.43
				0.128	forage	0	3.08, 3.22
						14	0.57, 0.59
					hay	17 (5)	0.99, 1.17
Conklin, MI; 2004 (04-13-R-1-MI)	5	Bluegrass; Kentucky	2	0.062	forage	0	5.89,7.01[4]
						14	0.78, 0.81
					hay	14 (1)	2.61, 2.72[4]
				0.124	forage	0	10.30[4], 11.70[4]
						14	0.37, 0.37
					hay	14 (2)	5.63, 5.68
			3	0.094	forage	0	9.67[4], 12.4[4]
						14	1.03, 1.12
					hay	14 (1)	3.96[4], 3.99
				0.125	forage	0	4.36, 4.37
						14	0.18, 0.19
					hay	14 (2)	0.68, 0.69[4]
Delavan, WI; 2004 (04-13-R-1-WI)	5	Bluegrass; Native WI	2	0.061	forage	0	3.46, 3.65
						14	0.24, 0.24
					hay	14 (4)	0.55, 0.60
				0.125	forage	0	4.27, 4.88
						14	0.32, 0.33
					hay	14 (2)	0.83, 0.89
			3	0.093	forage	0	4.64, 4.78
						14	0.33, 0.35
					hay	14 (4)	0.96, 0.99
				0.125	forage	0	1.92, 1.92
						14	0.13, 0.14
					hay	14 (2)	0.34, 0.38

TABLE C.3. *Residue Data from Grass Field Trials with Sulfosulfuron.*

Trial ID: City, State; Year (Trial ID #)	Zone	Crop; Variety	Treatment[1]	Total Rate (lb ai/A)	Commodity or Matrix	PHI[2] (days)	Residues[3] (ppm sulfosulfuron equivalents)
Carlyle, IL; 2004 (04-13-R-1-IL)	5	Bluegrass; Kentucky	2	0.061	forage	0	5.49, 5.58
						14	0.53, 0.57
					hay	14 (5)	1.73, 1.79
				0.126	forage	0	9.09, 9.66
						14	5.05, 5.70
					hay	14 (3)	6.21, 6.95
			3	0.092	forage	0	5.76, 6.50
						14	1.22, 1.27
					hay	14 (5)	1.79, 2.10
				0.123	forage	0	4.49, 4.70
						14	2.18, 2.90
					hay	14 (3)	3.52, 3.67
Magnolia, NC; 2004 (04-13-R-1-NC)	2	Bermudagrass; Coastal Hybrid Tifton 41	2	0.061	forage	0	3.51, 3.78
						14	0.05, 0.06
					hay	14 (3)	0.16, 0.16
				0.122	forage	0	4.62, 4.73
						7	0.94, 1.01
						14	0.55[4], 0.71[4]
						21	0.35[4], 0.36[4]
					hay	14 (2)	1.03, 1.19
						21 (2)	0.62, 0.72
						28 (2)	0.54, 0.62
			3	0.091	forage	0	4.10, 4.35
						14	0.07, 0.08
					hay	14 (3)	0.22, 0.25
				0.123	forage	0	2.40, 3.23
						7	0.50, 0.54
						14	0.33[4], 0.36[4]
						21	0.17, 0.23
					hay	14 (2)	0.75, 0.75
						21 (2)	0.42, 0.44
						28 (2)	0.35, 0.38

TABLE C.3. Residue Data from Grass Field Trials with Sulfosulfuron.

Trial ID: City, State; Year (Trial ID #)	*Zone*	*Crop; Variety*	Treatment[1]	Total Rate (lb ai/A)	Commodity or Matrix	PHI[2] (days)	Residues[3] (ppm sulfosulfuron equivalents)
Chula, GA; 2004 (04-13-R-1-GA)	2	Bermudagrass; Tift 85	2	0.064	forage	0	3.30, 3.31
						14	0.22, 0.23
					hay	14 (2)	0.42, 0.49
				0.129	forage	0	3.98, 4.22
						14	0.16, 0.18
					hay	14 (2)	0.24, 0.26
			3	0.096	forage	0	6.03, 6.59
						14	0.54, 0.57
					hay	14 (2)	1.34, 1.63
				0.126	forage	0	3.15, 3.30
						14	0.15, 0.17
					hay	14 (2)	0.18, 0.19
Swifton, AR; 2004 (04-13-R-1-AR)	4	Bermudagrass; Tifton 44	2	0.063	forage	0	2.95, 3.97
						14	0.09, 0.11
					hay	21 (1)	0.12, 0.14
				0.127	forage	0	5.26, 5.67
						14	4.66, 5.09
					hay	14 (2)	7.04, 7.23
			3	0.093	forage	0	4.44, 4.46
						14	0.21, 0.21
					hay	21 (1)	0.17, 0.19
				0.123	forage	0	2.16, 2.18
						14	1.29, 1.32
					hay	14 (2)	2.55, 2.58
Washington, LA; 2004 (04-13-R-1-LA)	4	Bermudagrass; Common	2	0.063	forage	0	5.09, 5.12
						14	0.94, 0.96
					hay	14 (1)	1.42, 1.56
				0.125	forage	0	2.46, 2.64
						14	0.43, 0.44
					hay	14 (2)	0.90, 0.91
			3	0.094	forage	0	5.74, 6.12
						14	0.79, 0.82
					hay	14 (1)	2.07, 2.26
				0.125	forage	0	1.77, 1.82
						14	0.39, 0.40
					hay	14 (2)	0.53, 0.57

TABLE C.3. Residue Data from Grass Field Trials with Sulfosulfuron.

Trial ID: City, State; Year (Trial ID #)	Zone	Crop; Variety	Treatment[1]	Total Rate (lb ai/A)	Commodity or Matrix	PHI[2] (days)	Residues[3] (ppm sulfosulfuron equivalents)
Brookshire, TX; 2004 (04-13-R-1-TX)	6	Bermudagrass; Common	2	0.063	forage	0	4.47, 4.91
						14	2.16, 2.23
					hay	14 (2)	2.95, 3.38
				0.127	forage	0	3.52, 3.88
						14	0.26, 0.33
					hay	14 (2)	0.79, 0.90
			3	0.095	forage	0	6.97, 7.90
						14	3.47, 3.56
					hay	14 (2)	4.73, 5.13
				0.126	forage	0	1.86, 2.24
						14	0.08, 0.08
					hay	14 (2)	0.19, 0.20
Ephrata, WA; 2004 (04-13-R-1-WA)	11	Rangeland Grass; Blue Grama	2	0.062	forage	0	8.28, 8.53
						14	0.33, 0.34
				0.125	forage	0	5.15, 5.21
						14	0.02, 0.02
					hay	14 (5)	0.06, 0.06
			3	0.094	forage	0	9.54, 10.10
						14	0.36, 0.37
				0.125	forage	0	2.44, 3.02
						14	0.01, 0.01
					hay	14 (5)	0.02, 0.02
American Falls, ID; 2004 (04-13-R-1-ID-1)	11	Rangeland Grass; Orchard Grass, Tall Fescue, Meadow Brome	2	0.063	forage	0	6.98, 7.78
						14	1.12, 1.15
				0.125	forage	0	3.40, 3.41
						14	0.07, 0.08
					hay	21 (7)	0.10, 0.10
			3	0.098	forage	0	11.40, 11.90
						14	1.15, 1.19
				0.129	forage	0	2.20, 2.22
						14	0.04, 0.05
					hay	21 (7)	0.09, 0.09
Fruitland, ID; 2004 (04-13-R-1-ID-2)	11	Rangeland Grass; Anatone Blue Bunch, Wheatgrass	2	0.061	forage	0	4.67, 5.43
						14	1.27, 1.37
			3	0.094	forage	0	7.32, 7.84
						14	2.21, 2.44

TABLE C.3. Residue Data from Grass Field Trials with Sulfosulfuron.

Trial ID: City, State; Year (Trial ID #)	Zone	Crop; Variety	Treatment[1]	Total Rate (lb ai/A)	Commodity or Matrix	PHI[2] (days)	Residues[3] (ppm sulfosulfuron equivalents)
Logan, UT; 2004 (04-13-R-1-UT)	9	Rangeland Grass; *Orchard Grass* and Tall Fescue	2	0.062	forage	0	3.98, 3.98
						14	1.53, 1.55
				0.124	forage	0	1.91, 1.92
						14	0.14, 0.15
					hay	19 (5)	0.28, 0.29
			3	0.097	forage	0	6.15, 6.17
						14	2.10, 2.29
				0.127	forage	0	0.99, 1.00
						14	0.06, 0.06
					hay	19 (5)	0.09, 0.09

[1] Treatment 2 = two applications at ~0.062 lb ai/A; Treatment 3 = one application at ~0.094 lb ai/A + one application at ~0.031 lb ai/A.
[2] Days hay was dried are reported in parentheses.
[3] Combined residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring.
[4] The highest value from replicate analyses is reported.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Sulfosulfuron.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined residues of sulfosulfuron and its metabolites containing the intact imidazopyridine ring (ppm)[1]						
			n	Min.	Max.	HAFT[4]	Median	Mean	Std. Dev.
Grass, forage	0.061-0.064[2]	0	26	2.95	8.53	8.41	4.59	5.00	1.58
		14	26	0.05	2.23	2.20	0.55	0.76	0.63
	0.091-0.098[3]	0	26	4.10	12.4	11.65	6.16	6.95	2.46
		14	26	0.07	3.56	3.52	0.81	1.21	0.98
	0.122-0.129[2]	0	24	1.91	11.7	11	4.68	5.16	2.6
		7	2	0.94	1.01	0.975	-	0.975	-
		14	24	0.02	5.7	5.38	0.350	1.14	1.84
		21	2	0.35	0.36	0.355	-	0.355	-
	0.123-0.129[3]	0	24	0.99	4.70	4.60	2.32	2.67	1.04
		7	2	0.50	0.54	0.52	-	0.52	-
		14	24	0.01	2.9	2.54	0.175	0.487	0.731
		21	2	0.17	0.23	0.20	-	0.20	-
Grass, hay	0.061-0.064[2]	14	14	0.16	3.38	3.17	1.49	1.47	1.11
		21	4	0.12	0.60	0.56	0.33	0.34	0.25
	0.091-0.098[3]	14	14	0.22	5.13	4.93	1.93	2.24	1.60
		21	4	0.17	1.43	1.40	0.78	0.79	0.70
	0.122-0.129[2]	14-17	18	0.24	7.23	7.14	1.11	2.80	2.72
		19-21	6	0.10	0.72	0.67	0.285	0.352	0.262
		28	2	0.54	0.62	0.58	-	0.58	-
	0.123-0.129[3]	14-17	20	0.02	3.67	3.60	0.625	0.998	1.14
		19-21	6	0.09	0.44	0.43	0.09	0.203	0.176
		28	2	0.35	0.38	0.365	-	0.365	-

[1] Residues reported as parent equivalents; note that results were not reported in this table for trials with RTI > 56 days.
[2] Treatment 2 = 1 application at ~0.062 lb ai/A (or two applications at ~0.062 lb ai/A).
[3] Treatment 3 = 1 application at ~0.094 lb ai/A (or one application at ~0.094 lb ai/A + one application at ~0.031 lb ai/A).
[4] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data reflect two broadcast foliar applications of a 75% WDG formulation of sulfosulfuron at a total rate of 0.122-0.129 lb ai/A on pasture (Bluegrass and Bermudagrass) and rangeland grasses. Forage was harvested on the day of and 14 days after application, and hay was cut 14-21 days after application and was collected following 1-7 days of field drying. An acceptable method was used for quantitation of residues in/on grass forage and hay, and the data are supported by acceptable storage stability data.

E. REFERENCES

DP#s:	237683 and 239109
Subject:	PP# 7F04840. New Chemical - Sulfosulfuron (i.e. MON37500, Maverick®) in/on Wheat. Evaluation of Residue Data and Analytical Methods.
From:	S. Chun
To:	J. Tompkins/V. Walters
Date:	28-SEP-1998
MRIDs:	44295702-04, 44295707-11, 44295713-14, 44295716-18, 44295735, 44309301

F. DOCUMENT TRACKING

RDI: Chemists: 20-SEP-2006
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Chemical: Sulfosulfuron

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